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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,789	09/29/2003	Jutaro Shudo	TEIK-006	2237
24353	7590	01/09/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			VANIK, DAVID L	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,789	SHUDO ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt is acknowledged of the applicant's Oath or Declaration filed on 12/30/2003.

Receipt is also acknowledged of the applicant's Information Disclosure Statement filed on 11/12/2003.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to a **storage stable composition** comprising a delayed type hypersensitivity inducer agent, classified in class 514, subclass 763.
 - II. Claims 10-15, drawn to a **sealed container** further comprising a storage stable composition, classified in class 604, subclass 403.
 - III. Claims 16-21, 27 drawn to a kit comprising a **storage stable composition** and a **topical patch preparation** further comprising a **fluid retaining region**, classified in class 424, subclass 443.
 - IV. Claims 22-25, drawn to a **method of making a topical patch and a method of administering a topical patch** to a subject, classified in class 424, subclass 402.

The inventions are distinct, each from the other because of the following reasons:

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2. Invention I and Inventions II-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I and Inventions II-III have different functions and effects. Specifically, Invention I is drawn to a storage stable composition comprising a delayed type hypersensitivity inducer agent whereas Inventions II and III are drawn to a **sealed container** further comprising a storage stable composition and a kit comprising a **storage stable composition** and a **topical patch preparation** further comprising a **fluid retaining region**, respectively. As such, Invention I and Inventions II-III are characterized by distinct scopes and a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

3. Inventions I, II, and III and Invention IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I-III and Inventions IV have different functions, modes of operations, and effects. Invention I is drawn to a storage stable composition comprising a delayed type hypersensitivity inducer agent, Invention II is drawn to a **sealed container** further comprising a storage stable composition and Invention III is drawn to a kit comprising a **storage stable composition** and a **topical patch preparation** further comprising a **fluid retaining region**. Occupying a patentably different scope, Invention IV is drawn to a **method of making a topical**

patch and a method of administering a topical patch to a subject. As such, Inventions I-III and Invention IV are characterized by distinct scopes and a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

4. Invention II and Invention III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II and Invention III have different functions and effects. Specifically, Invention II is drawn to a **sealed container** further comprising a storage stable composition whereas Invention III is drawn to a kit comprising a **storage stable composition** and a **topical patch preparation** further comprising a **fluid retaining region**, respectively. As such, Invention II and Invention III are characterized by distinct scopes and a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

5. Searching the inventions of Groups I – IV together would impose a search burden on the examiner. In the instant case, the search of a storage stable composition, a sealed container, a kit, and a method of making a topical patch would impose a search burden on the examiner.

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6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for each subset of Groups I – IV are not required for one another, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Due to the complexity of the action, examiner submitted the Election Restriction in writing in lieu of calling applicant's attorney.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

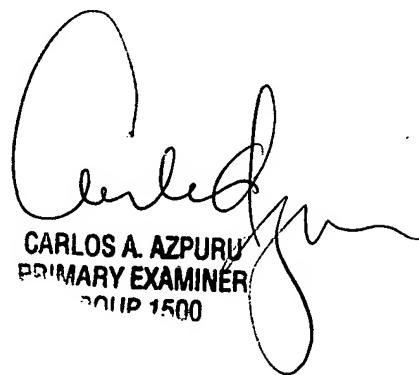
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615



12/27/05



CARLOS A. AZPURU
PRIMARY EXAMINER
2011P 1500